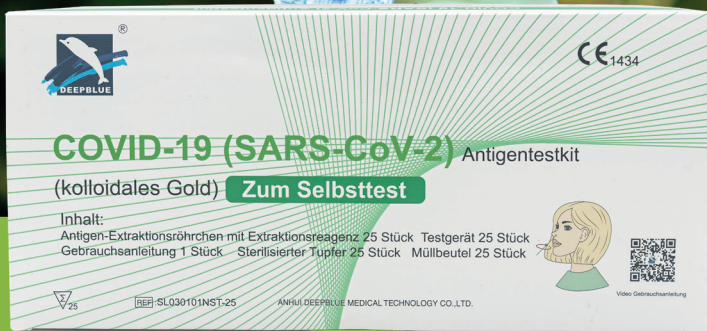




KINGLINE
GMBH



DEEPBLUE® COVID-19 ANTIGEN SCHNELLTEST



Zertifiziert
und Evaluiert



Zuverlässig sehr
genaue Ergebnisse



Persönliche
Experten-Beratung

1/4

Version: 1.0 | Freigabe: 15.12.2022

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Kingline GmbH | Am Altenbach 7 | 91341 Röttenbach



EINFACHE UND SICHERE
ANWENDUNG



ZUVERLÄSSIG SEHR
GENAUE ERGEBNISSE



SCHNELLES
TESTERGEBNIS



CE-ZERTIFIZIERT
(CE-1434)

PRODUKTBILDER



Vorderansicht 1er



Vorderansicht 1er Softpack



Vorderansicht 25er



Packungsinhalt (einzel)



DETAILINFORMATIONEN

CE-Kennzeichnung	CE-1434
Art der Probe	Anterior nasal
Anwendungsart	Laien
LoD-Wert	80 TCID 50/ml
Diagnostische Sensitivität	96,4 %
Diagnostische Spezifität	99,8 %
Haltbarkeit (ab Produktionsdatum)	24 Monate
Verfügbare Sprachen des Handbuchs	Deutsch

LOGISTIKDATEN

VPE	800 Stk. (1er-Packung) 1000 Stk. (1er-Softpack) 1250 Stk. (25er-Packung)
VPE Gewicht	22,5 kg (1er-Packung) 20 kg (1er-Softpack) 18 kg (25er-Packung)
VPE Maße (B x H x T)	60x55x56 cm (1er-Packung) 60x55x56 cm (1er-Softpack) 62x55x41 cm (25er-Packung)
VPE pro EPAL	8 VPE (6.400 Stk.) (1er-Packung) 8 VPE (8.000 Stk.) (1er-Softpack) 20 VPE (25.000 Stk.) (25er-Packung)
EPAL Gewicht	205 kg (1er-Packung) 175 kg (1er-Softpack) 370 kg (25er-Packung)
EPAL Maße (B x H x T)	80x120x238 cm (1er-Packung) 80x120x238 cm (1er-Softpack) 105x125x230 cm (25er-Packung)
EPAL pro LKW	33 EPAL (211.200 Stk.) (1er-Packung) 33 EPAL (264.000 Stk.) (1er-Softpack) 20 EPAL (500.000 Stk.) (25er-Packung)
Lagertemperatur	min. 2 °C; max. 30°C
Vereinzelbar	ja

DISTRITBUTION

Hersteller	Anhui Deepblue Medical Technology Co., Ltd. 4th Floor,D-1#Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, China
EC-REP	Luxus Lebenswelt GmbH Kochstr. 1, 47877 Willich, Germany
Importeur	Kingline GmbH Am Altenbach 7 91341 Röttenbach



CERTIFICATE

EC Certificate No. 1434-IVDD-445/2021

**EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Anhui Deepblue Medical Technology Co., Ltd.
4th Floor,D-1#Zone, Pearl Industrial Park, 106
Innovation Avenue, High-Tech Development Zone,
230088 Hefei, Anhui, China

in vitro diagnostic medical devices
for self-testing

COVID-19 (SARS-COV-2) Antigen Test Kit (Colloidal Gold)

SL030101NST-1,SL030101NST-2, SL030101NST-3, SL030101NST-5, SL030101NST-6, SL030101NST-7, SL030101NST-8,
SL030101NST-9, SL030101NST-10, SL030101NST-11, SL030101NST-12, SL030101NST-15, SL030101NST-16, SL030101NST-
17, SL030101NST-18, SL030101NST-19, SL030101NST-20, SL030101NST-25

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 22.07.2021



Issued under the Contract No. MD-96/2021
Application No: 183a/2021
Certificate bears the qualified signature.
Warsaw, 30.07.2021
Module A1

Anna
Małgorzata
Wyroba
Vice-President
Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.07.30
10:31:11 +02'00'

DECLARATION OF CONFORMITY

MANUFACTURER: ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,
High-Tech Development Zone , 230088 Hefei, Anhui, People's
Republic of China

EUROPEAN REPRESENTATIVE: Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

PRODUCT: COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

Models: SEE ATTACHMENT

REF: SEE ATTACHMENT

CLASSIFICATION: SELF-TESTING

EDMA CODE: 15 70 90 90 00

CONFORMITY ASSESSMENT ROUTE: Following the procedure relating to the EC Declaration of Conformity set out in Annex III Article 6 of Directive 98/79/EC.

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: EN ISO 13485:2016
EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:
2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO
15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO
14971:2012.

NOTIFIED BODY: Polish Center for Testing and Certification
469 Puławska Street, 02-844 Warsaw, Poland

(EN) CERTIFICATE(S): 2021-07-22

START OF CE-MARKING: 2021-07-22

PLACE, DATE OF ISSUE: HEFEI, 2021-07-28

SIGNATURE:

Chen Fengling

CHEN FENGLING

GENERAL MANAGER



CE1434

EC Declaration of Conformity

DOC-COVID-19 Ag(M/1)



**DECLARATION OF CONFORMITY
ATTACHMENT**

Specification	REF
1 piece per box	SL030101NST-1
2 pieces per box	SL030101NST-2
3 pieces per box	SL030101NST-3
5 pieces per box	SL030101NST-5
6 pieces per box	SL030101NST-6
7 pieces per box	SL030101NST-7
8 pieces per box	SL030101NST-8
9 pieces per box	SL030101NST-9
10 pieces per box	SL030101NST-10
11 pieces per box	SL030101NST-11
12 pieces per box	SL030101NST-12
15 pieces per box	SL030101NST-15
16 pieces per box	SL030101NST-16
17 pieces per box	SL030101NST-17
18 pieces per box	SL030101NST-18
19 pieces per box	SL030101NST-19
20 pieces per box	SL030101NST-20
25 pieces per box	SL030101NST-25

